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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,825	04/30/2001	Andrew J Garman	3764-75	3737

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,825

Applicant(s)

GARMAN ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 14 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 11/1, 12/1, 13/1 and 15 is/are rejected.
- 7) ☒ Claim(s) 7-10, 11/6, 12/6 and 13/6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 4, 5, 11/1, 12/1, 13/1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton et al.(WO 91/05519).

The reference of Leighton et al. discloses a device and method of use which includes an injection wall (22) and a cell injection needle (24) projecting from the wall. The device includes a device (32, 23, 26) for impelling cells toward the needle.

The instant claims differ by specifically reciting that the device includes a housing, inlets and outlets and a plurality of cell processing chambers.

Page 10, line 6, to page 11, line 14, discusses the use of a suspension of cells and the use of cross flushing. The reference is silent as to the structure which provides this function.

However, the use of inlets and/or outlets to provide a suspension of cells to a chamber and/or provide a flushing solution is known in the art. As a result, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with inlets and outlets for the known and expected result of providing a means recognized in the art for providing a suspension of cells and/or a flushing liquid. The use of a single structure as an inlet and outlet would have been merely an obvious matter in design choice while minimizing construction costs.

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With respect to the use of plural chambers, based merely on the number of cells to be processed, it would have been obvious to one of ordinary skill in the art to provide parallel and/or serial chambers for the known and expected result of processing a large number of cells without scaling-up the device and/or allow one to process different sizes of cells by using chambers of different sizes of wells.

With respect to the needle size, it would have been obvious to one of ordinary skill in the art to determine the optimum needle size based merely on the size of the cell to be treated while minimizing the damage to the membrane of the cell.

With respect to claims 11 and 12, Figures 4-6 depict the use of hollow or solid needles. Additionally, page 13, lines 9-17, discloses the use of electroporation as a means to transfer the material into the cells. The needle merely carries the material to be carried into the cell by electroporation. With respect to claim 15, page 9, lines 15-25, discloses the use of a suspension of cells.

***Allowable Subject Matter***

3. Claims 6 and 14 are allowed.
4. Claims 7-10, 11/6, 12/6 and 13/6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. The following is a statement of reasons for the indication of allowable subject matter:

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Claims 6, 11/6, 12/6, 13/6 and 14 would be allowable because the prior art of record fails to teach or fairly suggest a conduit which includes a cell injection needle wherein the cells enter the conduit through an inlet, contact the injection needle and then move through an outlet of the conduit.

With respect to claims 7-10, the prior art of record fails to teach or fairly suggest the use of a cell sensor which determines the presence of a cell on or near the injection needle and injection or extraction of material with respect to the cell is controlled in response to the cell sensor.

### ***Response to Arguments***

6. Applicant's arguments filed 05 June 2003 have been fully considered but they are not persuasive for the following reasons:

With respect to the 35 USC 102 prior art rejections of record, Applicants argue (see page 9, lines 1-10, of Applicants' response) that the limitation of original claim 3 has been incorporated into the language of claim 1 and since claim 3 was not anticipated by the references instant claim 1 would not be anticipated.

Applicants' comments are persuasive and the rejection under 35 USC 102 has been withdrawn.

With respect to the 35 USC 103 rejection of record applicants argue (See page 9, lines 11-22, of Applicants' response) that the rejection should be withdrawn because the subject matter of claim 2 was not rejected on obviousness grounds and claim 2 has been incorporated into claim 1.

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In response, Applicants' comments are not persuasive because claim 2 was rejected under 35 USC 102 rather than 35 USC 103.

Applicants also argue that the reference of Leighton fails to suggest a housing that includes the needles and an inlet and/or outlet.

In response, the Examiner is of the position while the exact structure is not disclosed, the reference of Leighton suggests the use of a housing and inlets and/or outlets in combination with the cell holding and piercing device in view of the language recited on page 10, line 30, to page 11, line 14, which discusses placing the apparatus (10) in a suspension of cells and the removal of cells by cross-flushing by application of a differential pressure. These suggested means for controlling the application to the device (10) would not be capable in the absence of a housing for containing the cell suspension and/or inlets or outlets for generating the cross-flushing differential pressure.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB